EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

PAULETTE SILBERMAN, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

SOLCO HEALTHCARE U.S., LLC; PRINSTON PHARMACEUTICAL INC. d/b/a SOLCO HEALTHCARE LLC; HUAHAI US INC.; ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.; AND JOHN DOES 1-100,

Defendants.

Civil Action No.:_____

Jury Trial Demanded

Complaint-Class Action

CLASS ACTION COMPLAINT

1. Plaintiff Paulette Silberman ("Plaintiff"), individually and on behalf of all others similarly situated, brings this action against Solco Healthcare U.S., LLC ("Solco"), Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC ("Prinston"), Huahai US Inc. ("Huahai"), Zhejiang Huahai Pharmaceuticals Co., Ltd. ("ZHP"), and John Does 1-100 ("John Does") (collectively, "Defendants"). Plaintiff's allegations are based upon personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

2. Plaintiff brings this action on behalf of herself and other Valsartan consumers who paid for Defendants' generic Valsartan that was adulterated through its contamination with an IARC- and EPA-listed probable human carcinogen known as N-nitrosodimethylamine ("NDMA").

3. At all times during the period alleged herein, Defendants represented and warranted to consumers that their generic Valsartan products were therapeutically equivalent to and otherwise the same as the brand name medication, DIOVAN®, were otherwise fit for their ordinary uses, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

4. However, for years, ZHP manufactured Defendants' Valsartan products in a manner that they were contaminated with NDMA, and Defendants negligently and willfully ignored warning signs regarding the operating standards at the ZHP manufacturing facilities in Linhai City , Zhejiang Province, China, and continued to allow ZHP to manufacture their Valsartan products for sale to consumers in the United States even after Defendants knew or should have known that their Valsartan products manufactured by ZHP contained or likely contained NDMA and/or other impurities.

5. These adulterated Valsartan drugs were introduced into the American market

potentially as far back as November 2011 by Defendants, for Defendants to profit from their sale to American consumers, such as Plaintiff and Class Members.. Plaintiff and Class Members paid for all or part of their contaminated Valsartan prescriptions that were illegally introduced into the market by Defendants and which were not fit for their ordinary use. Defendants have been unjustly enriched through the sale of these adulterated drugs since at least November 2011. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state law.

II. PARTIES

6. Plaintiff is a New Jersey resident. During the class period, she paid money for one or more of Defendants' Valsartan products. Defendants expressly and impliedly warranted to Plaintiff that their respective generic Valsartan products were the same as the brand name medication Diovan. Had the truth about the impurities within Defendants' products been made known, Plaintiff Silberman would not have paid for Defendants' Valsartan products. At all times relevant there were adequate alternative medications and therapies available to Plaintiff.

7. Solco is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. 8. Solco is a fully owned subsidiary of Prinston and ZHP.[1] At all times material to this case, Solco has been engaged in the manufacturing, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

8. Prinston is a Delaware limited liability company with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Prinston is a subsidiary of ZHP. At all times material to this case, Prinston has been engaged in the manufacturing, sale, and

[1] ABOUT SOLCO, http://solcohealthcare.com/about-solco.html (last visited Jan. 29, 2019).

distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

9. Huahai is a New Jersey corporation, with its principal place of business located at 2002 Eastpark Blvd., Cranbury, New Jersey 08512. Huahai is a subsidiary of ZHP. At all times material to this case, Huahai has been engaged in the manufacture, sale, and distribution of adulterated generic Valsartan in the United States, including in the State of New Jersey.

10. ZHP is based on investigation, information and belief, a corporation in China, located at Xunqiao, Linhai City, Zhejiang Province, 317024. ZHP also has a United States headquarters located at 2009 Eastpark Blvd., Cranbury, New Jersey 08512. At all times relevant to this case, ZHP has been the manufacturer of the contaminated Valsartan at issue in this Complaint, and has been involved in and/or responsible in whole or in part, for the distribution, sales, and marketing of the contaminated Valsartan both directly and through its subsidiaries and affiliates.

11. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of John Does 1 through 100, inclusive, are unknown to Plaintiff at this time. Plaintiff therefore sues these defendants using fictitious names. Each John Doe proximately caused damages to Plaintiff as alleged below, and each John Doe is liable to the Plaintiff for the acts and omissions alleged below as well as the resulting damages sustained by the Plaintiff. Plaintiff will amend this Complaint to allege the true names and capacities of the John Does when evidence reveals their identities.

12. At all times relevant to this Complaint, each of the John Does was the agent, servant, employee, and/or joint venturer of the other co-defendants and other John Does. Moreover, each Defendant and each John Doe acted in the full course, scope, and authority of that

agency, service, employment, and/or joint venture.

III. JURISDICTION AND VENUE

13. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action. In addition, this Court has original jurisdiction pursuant to 28 U.S.C. § 1331.

14. This Court has personal jurisdiction over Defendants because Plaintiff resides in and purchased and utilized the Valsartan at issue in New Jersey, and because Defendants have sufficient minimum contacts in and with New Jersey, and otherwise intentionally availed themselves of the markets within New Jersey through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

15. Venue is proper in this District because: Defendants reside in this District, 28 U.S.C. § 1391(b)(1); because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and because Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Valsartan Background

16. Valsartan is a medication which is used in the treatment of hypertension, heart failure, and post-myocardial infarction.

17. Valsartan is the generic name of the registered listed drug ("RLD") DIOVAN® ("Diovan"), which was marketed in tablet form by Novartis AG ("Novartis") beginning in July 2001 upon approval by the U.S. Food and Drug Administration ("FDA").

18. Globally, Diovan generated $5.6 billion in sales in 2011 according to Novartis's Form 20-F for that year, of which $2.33 billion was from the United States.

19. Diovan's FDA-approved label specifies its active and inactive ingredients. NDMA is not an FDA-approved ingredient of Diovan. Nor is NDMA an FDA-approved ingredient of any generic Valsartan product. Nor does any label known to Plaintiff include NDMA as an ingredient.

20. Although Novartis's Diovan patents expired in September 2012, Novartis was spared generic competition until approximately June 2014 because Ranbaxy Pharmaceuticals (the generic exclusivity holder) was unable to achieve FDA approval for its generic Diovan, thus effectively preventing other generic competition under the Hatch-Waxman Act, until Ranbaxy achieved FDA approval and began to market its generic product.

B. <u>The Generic Drug Approval Framework</u>

21. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

22. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

23. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

24. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is determined to be safe and

effective for the approved indication through clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product is assumed to be safe and effective for the same approved indication as the RLD.

25. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

26. And finally, a generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD]." 21 U.S.C. § 355(j)(2)(A)(v).

27. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant this through the inclusion of the same labeling as the RLD delivered to consumers in each and every prescription of its generic products.

28. According to the FDA, there are approximately fifteen ANDAs approved for generic Diovan, *i.e.*, Valsartan.

C. Background on Current Good Manufacturing Practices

29. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to assure they meet safety, quality, purity,

identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

30. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations with regard to a facility that is manufacturing drugs intended to be distributed in the United States.

31. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacting laws adopting or mirroring these federal standards.

32. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

33. Indeed, FDA regulations require a drug manufacturer to have "written procedures

for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

34. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

35. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

36. Additionally, a "quality control unit" must independently test drug products manufactured by another company on contract:

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

21 C.F.R. § 211.22(a).

D. ZHP's Linhai City Facilities Before the Recall

37. ZHP has Active Pharmaceutical Ingredient ("API") manufacturing facilities located in Linhai City, Zhejiang Province, China. According to ZHP's website, ZHP was one of the first Chinese companies approved to sell generic drugs in the United States, and ZHP remains one of

China's largest exporters of pharmaceuticals to the United States and European Union.

38. ZHP manufactures Solco, Prinston, and Huahai's Valsartan products, and Solco, Prinston, and Huahai thus have a quality assurance obligation with respect to ZHP's processes and finished products as set forth above pursuant to federal law.

39. ZHP has a history of deviations from FDA's cGMP standards that began almost as soon as ZHP was approved to export pharmaceuticals to the United States.

40. On or about March 27-30, 2007, the FDA inspected ZHP's facility at Xunqiao in Linhai City, Zhejiang Province, China. That inspection revealed "deviations from current good manufacturing processes (CGMP)."

41. The FDA inspected ZHP's the same facility again on November 14-18, 2016. The inspection revealed four violations of cGMPs. First, "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile are not followed." Second, ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Third, "[p]rocessing areas are deficient regarding the system for cleaning and disinfecting the equipment." Last, "data is not recorded contemporaneously."

42. On May 15-19, 2017, the FDA inspected ZHP's facility at Coastal Industrial Zone, Chuannan No. 1 Branch, Linhai City, Zhejiang Province, China. ZHP manufactures all of its Valsartan at this Chuannan facility. That inspection resulted in the FDA's finding that ZHP repeatedly re-tested out of specification ("OOS") samples until obtaining a desirable result. This practice allegedly dated back to at least September 2016 per the FDA's letter at the time. The May 2017 inspection also resulted in FDA's finding that "impurities occurring during analytical testing

are not consistently documented/quantitated."

43. Furthermore, for OOS sampling results, ZHP routinely invalidated these results without conducting an appropriate scientific investigation into the reasons behind the OOS sample result. In fact, in one documented instance, the OOS result was attributed to "pollution from the environment." This practice was part of a pattern and practice of systematic data manipulation designed to fail to detect and/or intentionally conceal and recklessly disregard the presence of harmful impurities such as NDMA.

44. The May 2017 inspection also resulted in a finding that ZHP's "facilities and equipment [were] not maintained to ensure [the] quality of drug product." This was based upon observations including the FDA's finding that equipment was rusting and rust was being deposited into drug product, equipment was shedding cracking paint into drug product, there was an accumulation of white particulate matter, and black metallic particles were in API batches.

E. FDA Announces Voluntary Recall of Defendants' Adulterated Valsartan

45. On or about July 13, 2018, the FDA announced that Defendants were voluntarily recalling their Valsartan products manufactured by ZHP.[2] The recall was for products distributed as early as October 2015. However, based upon investigation, it is likely that Defendants' Valsartan manufactured in November 2011 and beyond was also contaminated with NDMA.

46. Subsequently, the FDA announced numerous additional recalls of Valsartan and other similar products manufactured or distributed, and sold by Defendants and non-parties.[3] These recalls include Defendants' January 18, 2019 recall of Irbesartan containing unacceptable amounts of another carcinogenic adulterant, N-nitrosodiethylamine (NDEA). ZHP also manufactured this

[2] FDA News Release, FDA ANNOUNCES VOLUNTARY RECALL OF SEVERAL MEDICINES CONTAINING VALSARTAN FOLLOWING DETECTION OF IMPURITY, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm (last accessed Jan. 28, 2019).
[3] FDA UPDATES ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Jan. 28, 2019).

adulterated Irbesartan.

F. FDA's November 29, 2018 Warning Letter to ZHP

47. On November 29, 2018, the FDA issued Warning Letter 320-19-04 to ZHP based on its July 23 to August 3, 2018 inspection of its Chuannan facility.[4] The letter summarized "significant deviations from [cGMPs] for [APIs]." The FDA consequently informed ZHP that its "API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."

48. The FDA explained that ZHP repeatedly failed "to ensure that quality-related complaints are investigated and resolved," including complaints related to peaks of NDMA in its products as early as 2012.

49. ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." More specifically, ZHP "approved a valsartan API process change . . . that included the use of the solvent [redacted]. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities[, such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process."

50. The FDA added that ZHP "also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in [its]

[4] FDA, ZHEJIANG HUAHAI PHARMACEUTICAL 11/29/18, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628009.htm (last accessed Jan. 28, 2019).

valsartan API before [it] approved the process change. [ZHP is] responsible for developing and using suitable methods to detect impurities when developing, and making changes to, [its] manufacturing processes."

51. ZHP claimed that it had followed "common industry practice." Importantly, the FDA reminded ZHP that "common industry practice may not always be consistent with CGMP requirements and that [it is] responsible for the quality of drugs [it] produce[s]." The FDA consequently "strongly" recommended that ZHP hire a cGMP consultant and referred ZHP to four guides on cGMPs.

52. On September 28, 2018, the FDA stopped allowing ZHP to admit its drugs made at its Chuannan facility into the United States. The Warning Letter stated that "[f]ailure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at [ZHP's Chuannan facility] into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B)."

G. Defendants Knew that Their Valsartan Contained Unacceptably High Amounts of NDMA, a Probable Human Carcinogen

53. The FDA has concluded that NDMA is a "probable human carcinogen[] and should not be present in drug products."[5] Defendants' Valsartan was reported to have tested for between 15 and 30 micrograms of NDMA.[6]

54. NDMA is not an FDA-approved ingredient for branded Diovan or generic

[5] FDA UPDATES ON ANGIOTENSIN II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last accessed Jan. 28, 2019).
[6] FDA, LABORATORY ANALYSIS OF VALSARTAN PRODUCTS, https://www.fda.gov/Drugs/DrugSafety/ucm622717.htm (last accessed Jan. 28, 2019).

Valsartan. Moreover, none of Defendants' Valsartan products (or any Valsartan product, for that matter) identifies NDMA as an ingredient on the products' labels or elsewhere. This is because NDMA is a probable human carcinogen and is not approved to be included in Valsartan.

55. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the NDMA contamination almost immediately.

56. 21 C.F.R. § 211.110 contains the cGMP's regarding the "[s]ampling and testing of in-process materials and drug products." Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c). ZHP violated this and numerous other applicable regulations.

57. Defendants' own quality control units were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by ZHP.

58. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the NDMA contamination in Defendants' Valsartan products would have been discovered in or about November 2011. Defendants were thus on (at minimum) constructive notice that their Valsartan products were adulterated as early as that date.

59. However, there are indications that Defendants had actual knowledge of Valsartan's contamination with NDMA, and made efforts to conceal or destroy the evidence.

60. As set forth above, FDA investigators visited ZHP's facilities in May 2017. Among the numerous violations found, in the words of FDA inspectors, ZHP "invalidat[ed] [OOS] results

[without] scientific justification" and did not implement "appropriate controls . . . to ensure the integrity of analytical testing" and routinely disregarded sampling anomalies suggestive of impurities.

61. These discoveries by the FDA's investigators suggest that Defendants were specifically aware of impurities in the drugs being manufactured by ZHP, including specifically contamination of Defendants' Valsartan with NDMA. The efforts to manipulate data constituted an explicit effort to conceal and destroy evidence and to willfully and recklessly introduce adulterated Valsartan into the U.S. market.

62. Defendants were also specifically aware of ZHP's manufacturing issues based on Defendants' awareness of cGMP violations as early as November 2011, based on their own monitoring of ZHP and of the Valsartan products being manufactured at ZHP, and based on the FDA's inspections of ZHP's facilities in March 2007, November 2016, and May 2017.

63. Indeed, ZHP owns Huahai and Prinston, which owns Solco together with ZHP, so the subsidiary defendants are imputed with actual knowledge of ZHP's willful deviations from cGMPs. The subsidiary defendants also have offices in the same office building in Cranbury, New Jersey.

64. And yet, Defendants knowingly, recklessly, and/or negligently introduced adulterated Valsartan into the U.S. market that was contaminated with NDMA. Defendants failed to recall their generic Valsartan products because they feared permanently ceding market share to competitors. And, upon information and belief, Defendants issued the "voluntary" recall of their Valsartan products only after the FDA had threatened an involuntary recall.

H. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic Valsartan Products

65. Each Defendant made and breached express and implied warranties and also made

affirmative misrepresentations and omissions to consumers about their adulterated Valsartan products.

66. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[7] The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their Valsartan ANDAs. In securing FDA approval to market generic Valsartan in the United States as an Orange Book-listed therapeutic equivalent to Diovan, Defendants were required to demonstrate that their generic Valsartan products were bioequivalent to brand Diovan.

67. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

68. By introducing their respective Valsartan products into the United States market under the name "Valsartan" as a therapeutic equivalent to Diovan and with the FDA-approved label that is the same as that of Diovan, Defendants represent and warrant to physicians and patients that their products are in fact the same as and are therapeutically interchangeable with Diovan.

69. Furthermore, Solco states on its "About Solco" page of its website that "[b]y using the same active ingredients, [Solco] produce[s] products which are identical (equivalent) to the branded medication."[8]

70. On the "Drug Safety" page of Solco's website, Solco states that "Solco Healthcare

[7] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed Jan. 28, 2019).
[8] Solco, OVERVIEW, http://solcohealthcare.com/about-solco.html (last accessed Jan. 28, 2019).

is committed in providing . . . its patients with high quality, FDA-approved generic medications."[9]

71. Solco lists its Valsartan products on its website with the statement that the "Reference Listed Drug" is "Diovan®" along with a link to download Solco's Valsartan Prescribing Information.[10] Clicking the "Prescribing Information" link loads a .pdf of the Prescribing Information with a Solco URL address (http://www.solcohealthcare.com/uploads/product/info/valsartan-pi-artwork_170524_141555.pdf).

72. Prinston also lists its Valsartan as equivalent to Diovan.[11]

73. Huahai assisted Prinston in acquiring approval of its ANDA for Valsartan.

74. On its website, ZHP states that it "has established an independent, strict and sound quality mangement [sic] system in accordance with GMP."[12] ZHP further claims that it "ensure[s] that production is operated in accordance with GMP and product quality meets the required specifications."

75. ZHP's "workshops of formulation are designed in strict compliance with the international cGMP standard, where the most advanced automatic pharmaceutical production equipment in the world was introduced."[13]

76. Each Defendant's Valsartan product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved Valsartan label, Defendants, as generic manufacturers of Valsartan, made representations and express and implied warranties to consumers that the medication was a generic form of Diovan, and of the "sameness" of their

[9] Solco, TRADE PARTNER INFORMATION, http://solcohealthcare.com/trade-partner-information.html#DrugSafety (last accessed Jan. 28, 2019).
[10] Solco, VALSARTAN TABLETS, http://www.solcohealthcare.com/product/valsartan-tablets#NDC-43547-367-03 (last accessed Jan. 28, 2019).
[11] Prinston, PRODUCT LIST, http://www.prinstonpharm.com/Products_List.html#v (last visited Jan. 29, 2019).
[12] ZHP, QUALITY SYSTEM, http://en.huahaipharm.com/content.asp?info_kind=008 (last visited Jan. 29, 2019).
[13] ZHP, INTRODUCTION, http://en.huahaipharm.com/content.asp?info_kind=001002 (last visited Jan. 29, 2019).

products to Diovan, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

77. In addition, on information and belief, each Defendant affirmatively misrepresented and warranted to consumers through their labels, websites, brochures, and other marketing or informational materials that their Valsartan product was the equivalent of Diovan, and that it complied with cGMPs, contained only the ingredients identified on the products' FDA-approved labels, and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

78. The presence of NDMA in Defendants' Valsartan: (1) renders Defendants' Valsartan products non-bioequivalent (*i.e.*, not the same) to Diovan and thus non-therapeutically interchangeable with Diovan, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs thus rendering Defendants' Valsartan products non-therapeutically equivalent to Diovan, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' Valsartan containing an ingredient that is not also contained in Diovan, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each Defendant willfully, recklessly, and/or negligently failed to ensure their Valsartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

79. At all relevant times, Defendants have also impliedly warranted that their Valsartan products were merchantable and/or fit for their ordinary purposes.

80. Naturally, due to its status as a probable human carcinogen as listed by both the IARC and the U.S. EPA, NDMA is not an FDA-approved ingredient in Valsartan. The presence

of NDMA in Defendants' Valsartan means that Defendants have violated express and implied warranties to Plaintiff and Class Members. The presence of NDMA in Defendants' Valsartan results in Defendants' Valsartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Diovan), breaching Defendants' express warranties and implied warranty of merchantability and/or fitness for ordinary purposes.

81. For these and other reasons, Defendants' Valsartan is therefore adulterated as it was illegal for Defendants to have introduced such Valsartan in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

82. Adulterated Valsartan is essentially worthless. No consumer would knowingly purchase an adulterated Valsartan product or even be permitted to purchase adulterated Valsartan product because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated Valsartan products or competing medications with the same approved indications were available from other manufacturers.

I. Fraudulent Concealment and Tolling

83. Plaintiff's and Class Members' causes of action accrued no earlier than the date the FDA announced the recall of Defendants' generic Valsartan products.

84. Alternatively, any statute of limitations or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of ZHP's cGMP violations with respect to Valsartan, and of the fact that their Valsartan products were adulterated and contaminated with NMDA, and were not the same as brand Diovan.

85. For example, Defendants failed to reveal to the public that their Valsartan product

contained NDMA or was otherwise adulterated or non-therapeutically equivalent to Diovan until the FDA's recall announcement in July 2018. The inspection report which preceded the recall announcement was heavily redacted (including the names of the drugs affected by ZHP's cGMP violations), and prior inspection reports or warnings were not fully available to the public, if at all.

86. To the contrary, each Defendant continued to represent and warrant that their generic Valsartan products were the same as and therapeutically interchangeable with Diovan.

87. For instance, Huahai publicly announced on its website that, contrary to the FDA's pronouncements, that no impurity was discovered until June 2018.[14]

88. Because of this, Plaintiff and other Class Members did not discover, nor would they discover through reasonable and ordinary diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' intentional concealment, false and misleading explanations, and obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for Valsartan were appropriate for what they believed to be non-adulterated drugs despite their exercise of reasonable and ordinary diligence.

89. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff and other Class Members were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

[14] Huahai, PRESS RELEASE – UPDATE ON VALSARTAN API – A STATEMENT FROM THE COMPANY, https://www.huahaius.com/media.html (last accessed Jan. 28, 2019).

J. Plaintiff's Individual Facts

90. Plaintiff is a resident of Passaic, New Jersey.

91. On or about multiple dates, including but not limited to July 11, 2017, October 29, 2017, and March 26, 2018, Plaintiff purchased adulterated Valsartan manufactured, labeled, marketed, distributed, and/or sold by Defendants and bearing NDC Number 43547-0369-09. On these occasions, Plaintiff paid a co-pay of $15.00.

92. The adulterated Valsartan purchased by Plaintiff and manufactured, labeled, marketed, distributed, and/or sold by Defendants was not therapeutically equivalent to brand Diovan, was manufactured out of compliance with cGMPs, and was contaminated with NDMA.

93. Defendants illegally sold adulterated Valsartan to Plaintiff.

K. Extraterritorial Application of New Jersey Law as to Defendants

94. As alleged above, Defendants named herein maintain their corporate headquarters in New Jersey.

95. The express and implied warranties alleged herein were made from and originated from Defendants' respective headquarters in New Jersey.

96. The aforesaid conduct, including but not limited to misrepresentations and/or material omissions regarding the therapeutic equivalence of Defendants' Valsartan products to brand Diovan, and regarding Defendants' cGMP violations and/or distribution of adulterated Valsartan in the United States were made from Defendants' New Jersey headquarters.

97. Plaintiff intends to seek additional discovery to show that Defendants' warranties and breach thereof, and violations of consumer protection statutes, and other breaches of common law occurred and emanated primarily from New Jersey.

V. CLASS ACTION ALLEGATIONS

98. Plaintiff brings this action both individually and as a class action pursuant to Fed.

R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

> All individuals and entities in the United States of America and its territories and possessions who paid any amount of money, including out of pocket (for personal or household use) for Valsartan products manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since it implemented the manufacturing change that it approved in November 2011.

99. In the alternative, Plaintiff alleges sub-classes for all individuals and entities in each State, territory, or possession who paid any amount of money, including out of pocket for Valsartan product manufactured by or for Defendants, and marketed in the United States and its territories and possessions, at least since it implemented the manufacturing change that it approved in November 2011. Collectively, the foregoing Nationwide Class and alternative state sub-classes are referred to as the "Class."

100. Excluded from the Class are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

101. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create subclasses, including as the Court deems necessary.

102. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

103. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of thousands, and potentially millions of Valsartan consumers nationwide. The Class Members are therefore so numerous that joinder of all members

is impracticable.

104. **Commonality**: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiff and Class Members regarding their generic Valsartan products;

b. Whether each Defendant's Valsartan product was in fact the same as brand Diovan consistent with such express or implied warranties;

c. Whether each Defendant's Valsartan product was contaminated with NDMA;

d. Whether each Defendant's Valsartan product containing NMDA was adulterated;

e. Whether Defendants violated cGMPs regarding the manufacture of their Valsartan products;

f. Whether each Defendant affirmatively misrepresented or omitted facts that its Valsartan product was the same as brand Diovan and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs and/or was not adulterated;

h. Whether Plaintiff and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiff's and Class Members' causes of action accrued;

k. Whether Defendants fraudulently concealed Plaintiff's and Class Members' causes of action.

105. **Typicality**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same

interest in this matter as all other Class Members, and her claims arise out of the same set of facts and conduct as all other Class Members.

106. **Adequacy of Representation**: Plaintiff is committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class action, and federal court litigation. Accordingly, Plaintiff and her counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members she seeks to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

107. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

108. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiff's counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee the efficient

management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

109. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

110. Each Defendant expressly warranted that its Valsartan product was fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with brand Diovan. In other words, Defendants expressly warranted that their products were the same as Diovan.

111. Each Defendant sold Valsartan product that they expressly warranted were compliant with cGMP and/or not adulterated.

112. Each Defendant's Valsartan product did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and/or was adulterated.

113. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-

313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

114. At the time that each Defendant marketed and sold their Valsartan products, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as brand Diovan, and cGMP compliant and/or not adulterated. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other Class Members.

115. Each Defendant breached its express warranties with respect to their Valsartan products as they were not of merchantable quality, were not fit for their ordinary purposes, and did not comply with cGMP and/or were adulterated.

116. As a direct and proximate result of each Defendant's breach of express warranty and implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan products they purchased were so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

SECOND CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS (INDIVIDUALLY AND ON BEHALF OF THE CLASS)

117. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

118. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

119. Each Defendant was a merchant within the meaning of the above statutes.

120. Each Defendant's Valsartan product constituted "goods" or the equivalent within the meaning of the above statutes.

121. Each Defendant was obligated to provide Plaintiff and other Class Members reasonably fit Valsartan products for the purpose for which the products were sold, and to conform

to the standards of the trade in which Defendants are involved such that the products were of fit and merchantable quality.

122. Each Defendant knew or should have known that its Valsartan product was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to brand Diovan, and impliedly warranted that same was of merchantable quality and fit for that purpose.

123. Each Defendant breached its implied warranty because each Defendant's Valsartan product was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

124. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiff and other Class Members have been injured and suffered damages, in that Defendants' Valsartan product they purchased was so inherently flawed, unfit, or unmerchantable as to have essentially zero, significantly diminished, or no intrinsic market value.

THIRD CAUSE OF ACTION
FRAUD
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

125. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

126. Defendants affirmatively misrepresented material facts including, *inter alia*, that their Valsartan products contained the listed ingredients, were therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or were not adulterated.

127. Defendants failed to disclose material facts to render non-misleading its statements and representations about, *inter alia*, that their Valsartan products contained NMDA, were not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated.

128. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' Valsartan products – products which Defendants knew or should have known contained NMDA, were not therapeutically equivalent to brand Diovan and/or did not comply with GMPs and/or were adulterated. Plaintiff and other Class Members would not have paid the amounts they paid for Defendants' Valsartan products had they known the truth.

129. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

130. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' Valsartan products.

131. Defendants' misrepresentations and omissions were material.

132. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiff and other Class Members to pay for Defendants' Valsartan products.

133. But for these misrepresentations and omissions, Plaintiff and other Class Members would have not have paid for Defendants' Valsartan products.

134. To the extent applicable, Plaintiff and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' Valsartan products but-for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

135. Plaintiff and other Class Members were damaged by reason of Defendants'

misrepresentations and omissions alleged herein.

FOURTH CAUSE OF ACTION
VIOLATION OF NEW JERSEY CONSUMER FRAUD ACT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

136. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein..

137. Plaintiff and other members of the class are "persons" within the meaning of *N.J.S.A.* 56:8-1(d).

138. Defendant's conduct alleged herein constitutes a "sale" within the meaning of *N.J.S.A.* 56:8-1(e).

139. The New Jersey Consumer Fraud Act ("NJCFA") declares unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby." *N.J.S.A.* 56:8-2.

140. Defendants have engaged in unfair, unlawful and deceptive acts in trade and commerce which have the capacity and tendency to deceive and, in fact, did deceive Plaintiff and the class, and damaged Plaintiff and class members.

141. Defendants affirmatively misrepresented (and/or wrongfully concealed and omitted) that their Valsartan products contained the ingredients stated in the label and other documents about the medication, were therapeutically equivalent to brand Diovan and/or were manufactured in compliance with cGMPs and/or were not adulterated. In fact, Defendants' Valsartan products were contaminated with NDMA resulting in Defendants' Valsartan products

not being limited to the approved ingredients stated in the label and other documents about the medication, not being therapeutically equivalent to brand Diovan and not manufactured in compliance with cGMPs and in fact constituting adulterated pharmaceuticals.

142. Defendants committed unlawful, deceptive, and unconscionable trade practices by marketing, selling, and otherwise placing into the stream of commerce Defendants' Valsartan products on the premise they contained only the ingredients stated, were therapeutically equivalent to brand Diovan and/or manufactured in compliance with cGMPs and/or were not adulterated.

143. Defendants wrongfully concealed, suppressed, and omitted to disclose that its Valsartan products contained NDMA, were not therapeutically equivalent to brand Diovan and/or not manufactured in compliance with cGMPs and/or were in fact adulterated.

144. Defendants' misrepresentations and omissions had the capacity to mislead Plaintiff and Class Members into believing (i) that Defendants' Valsartan Products (i) contained only the ingredients stated in the label and other documents about the medication, (ii) were therapeutically equivalent to brand Diovan, (iii) were manufactured in accordance with cGMPs, and/or (iv) were not adulterated and were legal to sell in the United States, when the opposite was true.

145. Had Defendants not made misrepresentations or not omitted such facts, Plaintiff and the other class members would not have purchased Defendants' Valsartan products, and Defendants' Valsartan products would not have been available to Plaintiff because, among other reasons, it would have been illegal for Defendants to even introduce their Valsartan products into the United States. Plaintiff and the class members were injured as a result.

146. Because of Defendants' unlawful, deceptive, unfair, and unconscionable trade practices, Plaintiff and other members of the class have suffered injury and damages – an ascertainable loss – in an amount to be determined at trial. Pursuant to the NJCFA, this Court has

the power to enjoin Defendants' conduct.

147. Furthermore, the Court should find that the NJCFA applies extraterritorially because Defendants' conduct and violations of the NJCFA were orchestrated from and out of New Jersey. For instance, Defendants' personnel responsible for ensuring cGMP compliance are based in New Jersey; Defendants' personnel who executed quality agreements with ZHP are located in New Jersey; Defendants' personnel who maintain or oversee those who maintain Defendants' websites and other marketing materials are located in New Jersey, and Defendants' personnel responsible for the accuracy of the labels and other documents regarding the medication were located in New Jersey.

FIFTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

148. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

149. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus.

Prof. Code § 17200, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*; Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

150. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

151. Each Plaintiff and other Class Member are consumers or persons aggrieved by Defendants' misconduct within the meaning of the above statutes.

152. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances.

153. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages in an amount – an ascertainable loss – to be proved at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

154. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

155. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiff and other Class Members by virtue of the Plaintiff and other Class Members paying for Defendants' Valsartan products.

156. Defendants profited from the sale of the Valsartan products.

157. Defendants profited from introducing NDMA, a carcinogen, into the United States for human consumption.

158. Because Defendants' Valsartan products were adulterated, their distribution and sale in the United States was illegal.

159. Plaintiff and other Class Members were unjustly deprived of money obtained by Defendants as a result of the amounts paid for Defendants' Valsartan products. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiff and other Class Members as a result of their wrongful conduct alleged in this Complaint.

160. Plaintiff and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of their wrongful conduct.

SEVENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

161. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

162. Each Defendant owed a duty to Plaintiff and the other members of the Class to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, and sale of its Valsartan products.

163. Each Defendant owed a duty to Plaintiff and the Class to ensure that the Valsartan products it sold in the United States did not contain NDMA, contained only the ingredients stated, were therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

164. Each Defendant owed a duty of care to Plaintiff and the members of the Class because they were the foreseeable, reasonable, and probable users of Valsartan products. Each Defendant knew, or should have known, that its Valsartan product contained NDMA, did not

contain only the ingredients stated, was not therapeutically equivalent to brand Diovan and/or did not comply with cGMPs and/or were adulterated, and each was in the best position to uncover and remedy these shortcomings.

165. Each Defendant failed to fulfill its duty of care.. Each Defendant inadequately oversaw the manufacture, testing, labeling, distribution, marketing and sale of its own Valsartan product. Each Defendant knew that the aforesaid wrongdoing would damage Plaintiff and the members of the Class and wrongfully increase its own profits.

166. Each Defendant maintained or should have maintained a special relationship with Plaintiff and the members of the Class, as they were obligated to ensure that its Valsartan product complied with cGMPs and/or was not adulterated.

167. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the members of the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture, testing, labeling, distribution, marketing, and sale of its Valsartan product.

168. Each Defendant breached the duties owed to Plaintiff and the members of the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiff and the members of the Class.

169. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the members of the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF THE CLASS)

170. Plaintiff repeats and restates the foregoing allegations as if set forth fully herein.

171. Each Defendant owed a duty to Plaintiff and the members of the Class to use and exercise reasonable and due care in the manufacturing, testing, labeling, distribution, marketing, and sale of its Valsartan product.

172. Each Defendant owed a duty under the applicable law of every state to Plaintiff and the members of the Class to ensure that the Valsartan product it sold in the United States did not contain NDMA, contained only the listed ingredients, was therapeutically equivalent to brand Diovan and/or complied with cGMPs and/or was not adulterated.

173. Each Defendant owed a duty to Plaintiff and the Class because each State, territory, and possession has adopted and/or adheres to federal cGMP and adulteration standards.

174. Each Defendant failed to comply with federal cGMPs and/or federal adulteration standards.

175. As a result of each Defendant's failures to fulfill its aforesaid duties,, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the members of the Class.

176. As a direct and proximate result of each Defendant's negligent conduct, Plaintiff and the members of the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff pray for the following judgment:

A. An Order certifying this Action as a class action;

B. An Order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A Declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

D. An Order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

E. Payment to Plaintiff and Class Members of all damages, treble, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiff respectfully requests a trial by jury on all causes of action so triable.

TRIAL ATTORNEY DESIGNATION

Plaintiff designates Adam M. Slater as trial attorney.

Dated: January 29, 2019

RESPECTFULLY SUBMITTED,

Adam M. Slater (NJ Bar 046211993)
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Counsel for Plaintiff and the Class

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby further certify to the best of my knowledge that many related cases have been filed throughout the county. The Judicial Panel on Multidistrict Litigation ("JPML") has consequently scheduled a hearing for January 31, 2019, to decide whether to transfer all related cases to the District of New Jersey in Trenton. The JPML has designated these cases as MDL 2875 with the caption "In Re: Valsartan N-Nitrosodimethylamine (NDMA) Contamination Products Liability Litigation."

Dated: January 29, 2019

RESPECTFULLY SUBMITTED,

Adam M. Slater (NJ Bar 046211993)
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